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JUL 29 2005

Mr. Robert Doster
Senior Vice President of Scientific Affairs
Enzymatic Therapy
825 Challenger Drive
Green Bay, Wisconsin 54311-8328

Dear Mr. Doster:

This is in response to your letter of June 13, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter states that Enzymatic Therapy intends to make the following statement, among others, for the product HDL Booster™: "[R]emove LDL (bad) cholesterol from the blood vessel walls."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate diseases, namely, coronary heart disease because it describes an effect of the product on a characteristic sign or symptom of that disease (i.e., the product will prevent plaque formation by acting against one characteristic risk factor associated with plaque formation). This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

97S 0163 LET 836

Page 2 - Mr. Robert Doster

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal line extending to the right.

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Minneapolis District Office, Office of Compliance, HFR-CE840



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June 13, 2005

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL Booster™*	HDL cholesterol is called "good cholesterol" because its function is to remove LDL (bad) cholesterol from the blood vessel walls.*	Vitamin C (ascorbic acid), Vitamin E (mixed d-alpha tocopherols), Niacin (niacinamide), Vitamin B6 (pyridoxine HCl), Folic Acid, Vitamin B12 (cyanocobalamin), Magnesium (from Magnesium amino acid chelate), Selenium (L-Selenomethionine), L-Arginine (from L-arginine HCl), L-Carnitine (from L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol, Hawthorn Berry Extract, Taurine, Garlic, Grape Seed Extract, Grape Skin Extract, N-acetyl-L-cysteine, Alpha Lipoic Acid, Soy Isoflavones, Tocotrienols

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Title: Senior Vice President of Scientific Affairs

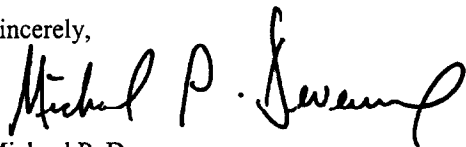
Date: 6/13/05

#1288

05-4365

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" being the most prominent.

Michael P. Devereux
Chief Financial Officer